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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/303,510	04/30/99	COLLISSON	E	54954/JPW/TV

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EXAMINER	
WINKLER, U	
ART UNIT	**PAPER NUMBER**
1645	9

DATE MAILED: 03/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/303,510	Applicant(s) COLLISSON ET AL.	
	Examiner Ulrike Winkler, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *18 January 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *2, 6 ,46-52, 55, 56, 61-64 and 83-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,6,46-52,55,56,61-64 and 83-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☒ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of group I in Paper No. 6 is acknowledged. Applicant's arguments against the restriction requirement mailed 11 November 1999 have been fully considered and are deemed persuasive. Applicants elected CD86 as the species to be examined in the instant application. The non-elected species CD80 is considered only in those claims involving CD86/CD80 fusion proteins. Therefore, the restriction requirement has been withdrawn and prosecution on the merits of all pending claims 2, 6, 46-52, 55, 56, 61-64 and 83-88 covering groups I and II are presented below.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The table in the specification at page 44, lines 23-37 and continued on page 45, lines 1-2 is indecipherable due to problems with the character alignment. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 46, 47, and 83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is noted that there is no written description of said "genomic DNA" in the specification. The specification discloses the cDNA for feline CD86 but it does not disclose the nucleotide sequence for the "genomic DNA". The specification does not disclose if there are introns and where they are located in the "genomic DNA". The art recognizes the differences between cDNA and "genomic DNA" which contains regulatory information and introns. Borriello et al. (Journal of Immunology 1995, see fig. 2) discloses the organization of "genomic DNA" for murine B7-2 and the differentially spliced products that are obtained. The instant specification does not disclose the location of the introns, whether there is differential splicing of the exons and what regulatory elements are included in the feline CD86 "genomic DNA".

Claims 2, 87 and 88 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not provide adequate written description for the claimed invention. There are two possible interpretations of the claims, one is that the vector codes for both nucleic acids and two individual protein products are obtained from one vector. The other interpretation is that the nucleic acids are fused to code for one fusion protein. There is

insufficient guidance and direction for the skilled artisan to make fusion proteins from the disclosed nucleic acids. It is unclear in what order the nucleic acids sequences are to be arranged. It is unclear from the claims or the specification what portion of each nucleic acid sequence is to be used. The specification does not provide an adequate written description of the fusion protein.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 55 and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rendered indefinite in that they only describe the composition by an arbitrary name. While the name itself may have some notion of activity of the protein, there is nothing in the claims which distinctly describes the protein and variants thereof. For example, others in the field may isolate the same protein and give it an entirely different name. Applicant should particularly point out and distinctly claim the "protein molecule and variant thereof" by claiming characteristics associated with the protein (e.g. activity, molecular weight, amino acid composition, N-terminal sequence, etc.). Claiming a biochemical molecule by a particular name given to the protein by the various workers in the field fails to distinctly claim what that protein is and what the compositions are made of.

Claims 2, 46, 47, and 83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of what is included in the "genomic DNA" of the instant application is unclear. Specifically, it is not clear what introns, exons and regulatory elements are to be considered part of the "genomic DNA".

Claims 2, 87 and 88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if the nucleic acid sequence of SEQ ID:5 and SEQ ID:1 are to be placed in the same vector with two different promoters allowing for expression of two separate proteins in one vector. Alternately, the two sequences can be fused to each other and expressed as one protein. If the claims are drawn to a fusion protein it is not clear in which order the sequences are to be fused.

Claims 2, 55 and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the vector in question contains the nucleotide sequence of CD80 or CD86.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 6, 46-52, 55, 56, 61-64, and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (U.S Pat. No. 5,942,607).

The instant invention is directed to the nucleic and amino acid sequence of feline CD86, oligonucleotide probes and vectors encoding the nucleic acid sequence of feline CD86.

Freeman et al. teach the human B7-2 (CD86) nucleic acid and amino acid sequence (see fig 8). Freeman et al also teach inserting the CD86 nucleic acid sequence into an expression vector (column 8, lines 4-28 and example 4, columns 30-33) and inserting the vector into a cell such as a COS cell (column 10, lines 33-47 and example 5, column 33-34) for expression.

Freeman et al. provides motivation and an expectation of success for determining members of CD86 in various species. The reference also provides oligonucleotides useful as diagnostic tools when labeled with a detectable marker (column 17, lines 27-35). Freeman et al. does not specifically teach the nucleotide and corresponding amino acid sequence of feline CD86.

At the time the invention was made the feline CD80 ligand had already been cloned. It would have been obvious at the time the invention was made to utilize the methods disclosed by Freeman et al (column 11, lines 50-62) to isolate the feline homologue of CD86. CD28 is expressed on resting T-cells and is the receptor for CD86. Binding of CD86 to CD28 causes resting T-cells to proliferate and secret IL-2. One of ordinary skill in the art would have been motivated to clone a ligand to CD28 from felines in order express and use these ligands as immunomodulators of the feline T cell mediated immune response (columns3, lines 36-38). Therefore, the instant invention is obvious in view of Freeman et al.

Claims 2, 55 and 86-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (U.S Pat. No. 5,942,607) and Hash (Gene Bank Direct Submission, 8 May 1996).

The instant invention is directed to the nucleic acid sequence of feline CD86 and CD80 expressed as a fusion protein in a vector.

The relevance of the Freeman et al. has been discussed above. In addition, Freeman et al teaches a fusion protein using B7-1 (CD80) and B7-2 (CD86) [column 3, lines 17-24]. Freeman et al. teaches the cloning of CD80 and CD86 as well as insertion of the nucleic acid sequences into expression vectors. Freeman et al does not disclose the nucleic acid sequence for feline

CD80 and feline CD86. The reference of Hash discloses the nucleic acid sequence of feline CD80.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a CD80/CD86 fusion protein in order to use the protein as an immunomodulator. One of ordinary skill in the art would have been motivated to clone the feline ligand to CD28 in order express and use these ligands as immunomodulators of the feline T cell mediated immune response (columns3, lines 36-38). Therefore, the instant invention is obvious in view of Freeman et al.

It appears that the specific sequence of SEQ ID: 5 and 6 are free of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at 703-308-3995.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JEFFREY STUCKER
PRIMARY EXAMINER